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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,114	01/24/2005	A. Brian Jones	20919YP	2116

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EXAMINER

KIFLE, BRUCK

ART UNIT PAPER NUMBER

1624

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/522,114	Applicant(s) JONES ET AL.	
	Examiner Bruck Kifle, Ph.D.	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-15, 17-19, 25 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-15, 17-19, 25 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02/21/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and remarks filed 02/21/06 have been received and reviewed.

Claims 2-15, 17-19, 25, and 30 are now pending in this application.

Claim Rejections - 35 USC § 112

Claims 2-15, 17-19, 25 and 30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) In claims 1, 2 and 15, the phrase “and pharmaceutically acceptable salts, esters and tautomers thereof” is inappropriate because this phrase requires all of them to be present at the same time in the claims. That is, while Applicants intend a compound or its salt, the claims require a compound and its salt to be present. The phrase could be rewritten as, for example, “or a pharmaceutically acceptable salt thereof” or use the Markush language “selected from the group consisting of a compound and salt.”

ii) The kinds of “esters” of the compound of formula I are unclear. Applicants argue “esters of compounds within the scope of Formula I are possible whenever a free carboxylic acid group is present. For example, compounds of this invention defined in claim 2 can contain a -COOH group when $R^2 = COOR^3$; $R^6 = -COOR^3$ or a group substituted with $-COOR^3$; or $R^7 = -COOR^3$ or a group substituted with $-COOR^3$; wherein $R^3 = H$. In claim 15, compound (20) contains a carboxyphenyl group, which can be esterified. In new claim 30, compound (12) contains a carboxyphenyl group, which can be esterified.

Pharmaceutically acceptable esters and their formation by reaction of a carboxylic acid group with an alcohol are standard knowledge to those skilled in the art. Additionally, examples of pharmaceutically acceptable esters are described in the specification at page 27, lines 29-30.

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Furthermore, examples of such esters are described in Example 18 (t-butyl ester) and Example 37 (ethyl ester) of the specification. As a result, the scope of the claimed subject matter, including pharmaceutically acceptable esters of the compounds of this invention, would be clear to one skilled in the art.”

Applicants first state that $R^2 = COOR^3$. R^3 is defined as H, phenyl or alkyl. That is, phenyl esters and alkyl esters are already claimed. The problem is what else is intended. That what is positively recited in the claims is well understood. It is unclear which other esters Applicants intend to include into the claims. Regarding claim 15, compound (20) and compound (12) of claim 30 which contain a carboxyphenyl group, it is unclear what is esterified or what kind of an ester is being formed.

Applicants also point to page 27, lines 29-30 for additional description. However, there was no description found here.

Finally, the compounds of examples 18 and 37 are already embraced by the claims. Thus, pharmaceutically acceptable esters of the compounds points to additional esterification, which is unclear.

Claims 3-14, 17-19 and 25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668. The examiner can normally be reached Tuesdays to Fridays between 8:30 AM and 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bruck Kifle, Ph.D.
Primary Examiner
Art Unit 1624

BK
March 7, 2006